

# SOLICITATION

## SECTION A - SOLICITATION/CONTRACT FORM

<b>1. Requisition or other Purchase Authority: 42 U.S.C 6A</b>		
<b>2. Request for Proposal (RFP) Number:</b> HHSNIHOLAO263(NINR)2017-NR	<b>3. Issue Date:</b> February 13, 2017	<b>4. Set Aside:</b> [ ] No [X] Yes See Part IV Section L
<b>5. Title :</b> National Institute of Nursing Research (NINR) Resource Center		
<b>6. ISSUED BY:</b> National Institutes of Health Office of Logistics&Acquisition Operations Office of Acquisitions 6011 Executive Blvd Suite 529 Rockville, MD 20852		<b>7. SUBMIT OFFERS TO:</b>  See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
<b>8.</b> Proposals for furnishing the services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 1 p.m. local time on March 8, 2017. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.		
<b>9.</b> This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS.  IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH FAR 52.212-1(f) LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
<b>10.</b> Offeror must be registered in the System for Award Management (SAM) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at <a href="http://www.sam.gov">http://www.sam.gov</a>		
<b><u>SUBMISSION DATE</u></b>  All proposals are due, electronically to Darlene.Johnson@nih.gov and a copy to Nora.Rivera@nih.gov no later than 1 p.m. Eastern Standard Time, on Wednesday, March 8, 2017.		<b><u>QUESTIONS SUBMISSION DEADLINE</u></b>  Interested offerors shall submit questions electronically to <a href="mailto:Darlene.Johnson@nih.gov">Darlene.Johnson@nih.gov</a> and a copy to <a href="mailto:Nora.Rivera@nih.gov">Nora.Rivera@nih.gov</a> no later than Monday, February 20, 2017, 12:00 p.m. Eastern Standard Time. Companies that previously submitted proposal may do so again. Collect calls will not be accepted. No Phone Calls Please.

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## **SECTION B - SERVICES AND PRICES/COSTS**

### **ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES**

The purpose of the proposed contract is to establish a Resource Center to assist the NINR Division of Intramural Research (DIR) with specific research process tasks.

### **ARTICLE B.2. PRICES/COSTS**

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

### **ARTICLE B.3. ADVANCE UNDERSTANDINGS**

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

- a. Subcontracts
- b. Consultants
- c. Scientific Meetings
- d. Equipment/Property

#### **e. Non-Personal Services and Inherently Government Functions**

1. Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the Contracting Officer's Technical Representative (COTR) to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All individual employee assignments, and daily work direction, shall be given by the applicable employee supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

2. Pursuant to FAR 7.5, the Contractor shall not perform any inherently Governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change the contract and that if the other contractor believes this communication to be a direction to change their contract, they should notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

3. The Contractor shall insure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of the contract, including those related to the Government's right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

#### **F. Special Copyright Provisions**

1. In accordance with FAR Clause 52.227-14, Rights in Data General, the Contractor shall seek written permission from the Contracting Officer before establishing a copyright for any software and associated data generated under this contract. Additionally, the Government shall be provided a paid-up, world-wide, irrevocable, nonexclusive license to all rights under any copyright obtained.

#### **G. Contract Number Designation**

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the contract number that appears on the face page of the contract as follows: Contract No. HHSN2632017xxxxx.

### **SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT**

#### **ARTICLE C.1. STATEMENT OF WORK**

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

#### **ARTICLE C.2. REPORTING REQUIREMENTS**

All reports required herein shall be submitted in electronic format and submitted to the Contracting Officer's Representative and Contracting Officer identified under Section F. Deliverables.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Making Files Accessible."

- a. **Technical Progress Reports**

1. Refer to the deliverables in the attached Statement of Work in SECTION J - List of Attachments.

- b. **Other Reports/Deliverables**

1. **Information Security and Physical Access Reporting Requirements**

The Contractor shall submit the following reports as required by the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract. Note: Each report listed below includes a reference to the appropriate subparagraph of this article.

- a. **Roster of Employees Requiring Suitability Investigations**

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within fourteen (14) calendar days of the effective date of the contract. (Reference the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

- b. **Reporting of New and Departing Employees**

The Contractor shall notify the Contracting Officer's Representative (COR) and Contracting Officer within five (5) working days of staffing changes for positions that require suitability determinations as follows:

- a. **New Employees who have or will have access to HHS Information systems or data:** Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.
- b. **Departing Employees:** 1) Provide the name, position title, and security clearance level held by or pending for the individual; and 2) Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the COR and/or Contracting Officer upon request.

(Reference the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

- c. **Contractor - Employee Non-Disclosure Agreement(s)** The contractor shall complete and submit, with five (5) working days, a signed and witnessed "Commitment to Protect Non-Public Information - Contractor Agreement" form for each contractor and subcontractor employee who may have access to non-public Department information under this contract. This form is located at: <https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf>.

(Reference the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

## 2. Section 508 Annual Report

The contractor shall submit an annual Section 508 report in accordance with the schedule set forth in the ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY Article in SECTION H of this contract. The Section 508 Report Template and Instructions for completing the report are available at: <http://www.hhs.gov/web/508/contracting/technology/vendors.html> under "Vendor Information and Documents."

## **SECTION D - PACKAGING, MARKING AND SHIPPING**

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

## **SECTION E - INSPECTION AND ACCEPTANCE**

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, TBD is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:  
National Institutes of Health  
National Institute of Nursing Research

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

The Government reserves the right to an Inspection period of 30calendar days, unless a different time period is stated when (the Record of Call/elsewhere in the contract). The receiving report, completed and signed by the appropriate official, constitutes acceptance and shall be acknowledged to the payment office (OFM).

- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-6, Inspection Time-and Material and Labor Hour** (May 2001).

Alternate I (April 1984) is applicable to this contract.

## SECTION F - DELIVERIES OR PERFORMANCE

### ARTICLE F.1. PERIOD OF PERFORMANCE

- a. The period of performance of this contract shall be from April 5, 2017 through April 4, 2018.
- b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Period
1	April 5, 2018 - April 4, 2019
2	April 5, 2019 - April 4, 2020

### ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the attached Statement of Work. See SECTION J - List of Attachments.

### ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <https://www.acquisition.gov/?q=browsefar>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

**52.242-15, Stop Work Order** (August 1989)

**Alternate I** (April 1984) is applicable to this contract.

## SECTION G - CONTRACT ADMINISTRATION DATA

### ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract: **TBD**

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

[The alternate COR is responsible for carrying out the duties of the COR only in the event that the COR can no longer perform his/her duties as assigned.]

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

### ARTICLE G.2. KEY PERSONNEL, HHSAR 352.237-75 (December 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title

### ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

### ARTICLE G.4. INVOICE SUBMISSION

- a. Invoice Instructions for NIH Fixed-Price/Time and Materials Type Contracts, NIH(RC)-2, are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.



1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

- a. The original invoice shall be submitted to the following **designated billing office**:

National Institutes of Health  
Office of Financial Management  
Commercial Accounts  
2115 East Jefferson Street, Room 4B-432, MSC 8500  
Bethesda, MD 20892-8500

- b. One electronic copy of the invoice shall be submitted to the following **approving official**:

Contracting Officer, Team 1  
Office of Logistics and Acquisition Operations  
Office of Acquisitions

E-mail:

The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. ***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

The Contractor shall include on the face page of each invoice, the Central Point of Distribution mailbox below. Do not send invoices to the CPD mailbox:

Central Point of Distribution:

## **ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

### **a. Contractor Performance Evaluations**

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually.

Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

### **b. Electronic Access to Contractor Performance Evaluations**

Contractors may access evaluations through a secure Web site for review and comment at the following address:

<http://www.cpars.gov>

## **SECTION H - SPECIAL CONTRACT REQUIREMENTS**

### **ARTICLE H.1. HUMAN SUBJECTS**

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

### **ARTICLE H.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS**

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

### **ARTICLE H.3. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS IN CLINICALTRIALS.GOV**

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_cong\\_public\\_laws&docid=f:publ085.110.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf), Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov and imposes new requirements that apply to specified "applicable clinical trials," including those supported in whole or in part by NIH funds. FDAAA requires:

- the registration of certain "applicable clinical trials" (see Definitions at: [http://grants.nih.gov/ClinicalTrials\\_fdaaa/definitions.htm](http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm)) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

In addition, the Contractor shall notify the Contracting Officer's Representative (COR), with the trial registration number (NCT number), once the registration is accomplished. This notification may be included in the Technical Progress Report covering the period in which registration occurred, or as a stand alone notification.

The Government is the Sponsor, therefore the "Responsible Party" for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov ( <http://www.ClinicalTrials.gov>).

Additional information is available at: <http://prsinfo.clinicaltrials.gov> .

#### **ARTICLE H.4. ACKNOWLEDGEMENT OF FEDERAL FUNDING**

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

#### **ARTICLE H.5. FEDERAL GOVERNMENT HOLIDAYS**

a. The Government hereby provides notification that Government personnel observe the listed days as holidays:

- (1) New Year's Day (6) Labor Day
- (2) Martin Luther King's Birthday (7) Columbus Day
- (3) President's Day (8) Veterans' Day
- (4) Memorial Day (9) Thanksgiving Day
- (5) Independence Day (10) Christmas Day

b. In addition to the days designated as holidays, the Government observes the following days:

- (1) Any other day designated by Federal Statute
- (2) Any other day designated by Executive Order
- (3) Any other day designated by the President's Proclamation

c. When any such day falls on a Saturday, the following Monday is observed. Except for designated around-the-clock or emergency operations, Contractor personnel will not be able to perform on-site under this contract with NIH on holidays set forth above. The Contractor will not charge any holiday as direct charge to the award.

d. It is understood and agreed between the Government and the Contractor that observance of such days by Government personnel shall not otherwise be a reason for an additional period of performance, or entitlement of compensation except as set forth within the award.

e. Nothing in this clause abrogates the rights and responsibilities of the parties relating to stop work provisions as cited in other sections of this contract.

#### **ARTICLE H.6. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION**

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

#### **ARTICLE H.7. PRIVACY ACT, HHSAR 352.224-70 (December 2015)**

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct in CFR 45 part 5b and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent

as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement: (a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and (b) specifies the disposition to be made of such records upon completion of contract performance.

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: [http://www.access.gpo.gov/nara/cfr/waisidx\\_06/45cfr5b\\_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html).

The Privacy Act System of Records applicable to this project is Number 09-25-0118. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: <http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm>.

## ARTICLE H.8. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-8, Option to Extend Services set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the price of the contract will be increased as set forth in the OPTION PRICES Article in SECTION B of this contract.

## ARTICLE H.9. INFORMATION AND PHYSICAL ACCESS SECURITY

### A. HHS-Controlled Facilities and Information Systems Security

- a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:
  1. HHS-OCIO Information Systems Security and Privacy Policy ( <http://www.hhs.gov/ocio/policy/#Security> )
  2. HHS HSPD-12 Policy Document, v. 2.0 ( <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf> )
  3. Information regarding background checks/badges ( <http://idbadge.nih.gov/background/index.asp> )
- c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

[ ] **Level 6: Public Trust - High Risk.** Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[X] **Level 5: Public Trust - Moderate Risk.** Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[X] **Level 1: Non-Sensitive.** Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

- d. The personnel investigation procedures for Contractor personnel require that the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with fingerprinting. More restricted positions - i.e., those above non-sensitive, require more extensive documentation and investigation.

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: [https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster\\_10-15-12.xlsx](https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx).

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract.

Contractors may begin work after the fingerprint check has been completed.

- e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.
- f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the additional investigation(s).
- g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.

- i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

## **B. Additional NIH Requirements**

### **1. INFORMATION SECURITY TRAINING**

The contractor shall comply with the below training:

#### **a. Mandatory Training**

- i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information, shall complete the NIH Computer Security Awareness Training course at <http://irtsectraining.nih.gov/> before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.
- ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COR and/or Contracting Officer upon request.

#### **b. Role-based Training**

HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance about "NIH Information Security Awareness and Training Policy," at: <https://ocio.nih.gov/InfoSecurity/Policy/Documents/Final-InfoSecAwarenessTrainPol.doc>.

The Contractor shall maintain a list of all information security training completed by each contractor/subcontractor employee working under this contract. The list shall be provided to the COR and/or Contracting Officer upon request.

#### **c. Rules of Behavior**

The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior ( <https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx> ), which are contained in the NIH Information Security Awareness Training Course <http://irtsectraining.nih.gov>.

### **2. PERSONNEL SECURITY RESPONSIBILITIES**

The contractor shall comply with the below personnel security responsibilities:



- a. The Contractor shall notify the Contracting officer and the COR **within five working days** before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.
- b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.
- c. **Departing contractor employees:** The Contractor shall provide the COR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist ( <https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf>) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COR upon request.
- d. **Commitment to Protect Non-Public Departmental Information and Data.**

The Contractor, and any subcontractors performing under this contract, shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: <https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf>. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

### 3. **LOSS AND/OR DISCLOSURE OF PERSONALLY IDENTIFIABLE INFORMATION (PII) - NOTIFICATION OF DATA BREACH**

The Contractor shall report all suspected or confirmed incidents involving the loss and/or disclosure of PII in electronic or physical form. Notification shall be made to the NIH Incident Response Team (IRT) via email ( [IRT@mail.nih.gov](mailto:IRT@mail.nih.gov)) within one hour of discovering the incident. The Contractor shall follow up with IRT by completing and submitting one of the applicable two forms below within three (3) work days of incident discovery:

NIH PII Spillage Report at: [https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH\\_PII\\_Spillage\\_Proced.doc](https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_PII_Spillage_Proced.doc)

NIH Lost or Stolen Assets Report at: [https://ocio.nih.gov/InfoSecurity/Policy/Documents/ISSO\\_Stolen\\_Device-Media\\_Handling\\_Procedures.doc](https://ocio.nih.gov/InfoSecurity/Policy/Documents/ISSO_Stolen_Device-Media_Handling_Procedures.doc)

## **ARTICLE H.10. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL**

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the Contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each Contractor employee's computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

## **ARTICLE H.11. CONFIDENTIALITY OF INFORMATION**

- a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
- b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
- e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

The following information is covered by this article: **All tasks performed and deliverables listed in the SOW. All clinical trials data, intellectual property, proprietary information and subject/participant information.**

## **ARTICLE H.12. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE**

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The website to file a complaint on-line is: <http://oig.hhs.gov/fraud/hotline/> and the mailing address is:

US Department of Health and Human Services  
Office of Inspector General  
ATTN: OIG HOTLINE OPERATIONS



P.O. Box 23489  
Washington, D.C. 20026

## **PART II - CONTRACT CLAUSES**

### **SECTION I - CONTRACT CLAUSES**

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at:

<https://oamp.od.nih.gov/DGS/reference-material-prospective-offerors-and-contractors>

#### **ARTICLE I.1. GENERAL CLAUSES FOR A TIME AND MATERIAL OR A LABOR HOUR CONTRACT**

#### **ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES**

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

- a. *FAR Clause 52.204-13, System for Award Management Maintenance (October 2016) is deleted in its entirety and FAR Clause 52.204-12, Unique Entity Identifier Maintenance (October 2016) is substituted therefor.*

*FAR Clause 52.232-33, Payment By Electronic Funds Transfer--System for Award Management (July 2013) is deleted in its entirety and FAR Clause 52.232-34, Payment by Electronic Funds Transfer--Other Than System for Award Management (July 2013) is substituted therefor.*

**FAR 52.222-3, Convict Labor (JUNE 2003)**

**FAR 52.222-19, Child Labor--Cooperation with Authorities and Remedies (APR 2012)**

**FAR 52.222-21, Prohibition of Segregated Facilities (FEB 1999)**

**FAR 52.222-35, Equal Opportunity for Veterans (SEP 2010)**

**FAR 52.222-36, Affirmative Action for Workers with Disabilities (OCT 2010)**

- b. *FAR Clause 52.222-54, Employment Eligibility Verification (October 2015) is deleted in its entirety.*

**52.243-3 Changes--Time-and-Materials or Labor-Hours.**

## ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

### a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (October 2015).

2. FAR Clause **52.217-8, Option to Extend Services** (November 1999).

"..The Contracting Officer may exercise the option by written notice to the Contractor within 60 days of exercising the option.

3. FAR Clause **52.219-6, Notice of Total Small Business Set-Aside** (November 2011).

**Alternate I** (November 2011) is not applicable to this contract.

**Alternate II** (November 2011) is not applicable to this contract.

4. FAR Clause **52.219-13, Notice of Set-Aside of Orders** (November 2011).

5. FAR Clause 52.222-26, **Equal Opportunity** (September 2016)

6. FAR Clause **52.224-2, Privacy Act** (April 1984).

7. FAR Clause **52.227-17, Rights in Data--Special Works** (December 2007).

8. FAR Clause **52.232-18, Availability of Funds** (April 1984).

### b. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

## ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

### a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 2000).

a. The Government may extend the term of this contract by written notice to the Contractor within 30 days; provided that the Government gives the Contractor a preliminary written notice of

its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.

- b. If the Government exercises this option, the extended contract shall be considered to include this option clause.
- c. The total duration of this contract, including the exercise of any options under this clause, shall not exceed 36 months.

- a. FAR Clause **52.222-41, Service Contract Labor Standards** (May 2014).
- b. FAR Clause **52.222-43, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (Multiple Year And Option Contracts)** (May 2014).
- c. FAR Clause **52.222-44, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment** (May 2014).
- d. FAR 52.222-55 **Minimum Wages Under Executive Order 13658** (December 2015)

## PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

### SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

#### SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (Non R & D)	
Attachment 2:	Statement of Work	
Attachment 3:	Section K - Representations, Certifications, and Other Statements of Offerors	
Attachment 4:	Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement	<a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Nondisclosure.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Nondisclosure.pdf</a>

#### TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 5:	Technical Proposal Cost Summary	<a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf</a>
Attachment 6:	Summary of Related Activities	<a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf</a>
Attachment 7:	HHS Section 508 Product Assessment Template	<a href="http://www.hhs.gov/web/508/contracting/technology/vendors.html">http://www.hhs.gov/web/508/contracting/technology/vendors.html</a>

#### BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 8:	Proposal Summary and Data Record, NIH-2043	<a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf</a>
Attachment 9:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	<a href="https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee-and-labor-hours">https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee-and-labor-hours</a>  <a href="https://oamp.od.nih.gov/sites/default/files/DFASDocs/buscntrectprpslsprdsht08-2014_508.xlsx">https://oamp.od.nih.gov/sites/default/files/DFASDocs/buscntrectprpslsprdsht08-2014_508.xlsx</a>
Attachment 10:	Offeror's Points of Contact	<a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf</a>
Attachment 11:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="http://www.gsa.gov/portal/forms/download/116430">http://www.gsa.gov/portal/forms/download/116430</a>

**INFORMATIONAL ATTACHMENTS**

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 12:	Invoice Instructions for NIH Fixed Price Contracts NIH(RC)-2	<a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc2_508.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc2_508.pdf</a>
Attachment 13:	Privacy Act System of Records	<a href="http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm">http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm</a>
Attachment 14:	Roster of Employees Requiring Suitability Investigations	<a href="https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx">https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx</a>

## **PART IV - REPRESENTATIONS AND INSTRUCTIONS**

### **SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS**

#### **IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :**

1. Go to the **System for Award Management (SAM)** and complete the Representations and Certifications. The SAM website may be accessed at: <http://www.sam.gov> ; and
2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**  
**SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS**  
which is included as an Attachment in Section J-LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation.

If you are unable to access this SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

3. FAR Clause 52.204-19 **Incorporation by Reference of Representations and Certifications** (December 2014).

The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

(End of Clause)

## SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

### 1. GENERAL INFORMATION

#### a. PROPOSAL SUBMISSION: Amendments to 52.212-1

##### **SUBMISSION DATE**

**All proposals are due, electronically to Darlene.Johnson@nih.gov and a copy to Nora.Rivera@nih.gov no later than 1 p.m. Eastern Standard Time, on Wednesday, March 8, 2017.**

##### **QUESTIONS SUBMISSION DEADLINE**

**Interested offerors shall submit questions electronically to Darlene.Johnon@nih.gov and a copy to Nora.Rivera@nih.gov no later than Monday, February 20, 2017, 12:00 p.m. Eastern Standard Time. Companies that previously submitted proposal may do so again. Collect calls will not be accepted. No Phone Calls Please.**

##### **FORMAT**

\*\*\*Proposal shall be in 3 volumes: Technical, Past Performance and Price. The volumes shall be separate and complete. The volumes shall be separate and complete, so that evaluation of one may be accomplished independently of, and concurrently with, the evaluation of the other. No pricing information shall be provided in volume's 1 and 2\*\*\*

\*\*\*The total number of pages for the technical quote shall not exceed fifty (50) pages, using 1" margins, single spaced, font type Time New Roman, and a font size of 12.

\*\*\*The solicitation does not commit the Government to pay any cost for the preparation and submission of a quote or proposal. It is also advised that the Contracting Officer (CO) is the only individual who can legally commit and obligate the Government to the expenditure of public funds in connection with the proposed acquisition.

Proposals received will first be evaluated from a technical standpoint without regard to proposed cost. Those proposals considered to be technically acceptable will then be evaluated from a financial and management standpoint.

Technical factors are significantly more important than cost or price. It is pointed out, however, that should technical competence between offerors be considered approximately the same, then cost or price could become primary.

NINR will base its award decision using a best value analysis that results in the most advantageous acquisition for the government. NINR's acquisition strategy used to obtain best value may result in an award to other than the lowest priced, technically rated offeror. Best value analysis spans a continuum from the lowest priced, technically acceptable proposal to those proposals in which tradeoffs between price, past performance, and each offeror's technical solution is evaluated. This tradeoff process (see FAR 15.101-1) depends on the government's assessment of quality factors, including but not limited to past performance, compliance with solicitation requirements, technical excellence, management capability, personnel qualifications and prior experience, and price.

FAR 52.212-3 Offeror Representations and Certifications-Commercial Items. (APR 2012)

The Government intends to evaluate proposals and, if necessary conduct discussions with all responsible Offerors within the competitive range. The award will be made to the Offeror whose proposal conforms to the



terms and conditions of the solicitation and award may be made to other than the lowest priced or the highest technically rated offer.

Relative importance and trade-offs. The Government will base the determination of best value on performance, and the other evaluation factors identified elsewhere in this solicitation. The determination of best value also considers the relative importance of the evaluation factors. Technical factors and past performance when combined are significantly more important than price. It is pointed out; however, should technical competence between Offerors be considered approximately the same, then price could become primary.

NIH will base its award decision using a best value analysis that results in the most advantageous acquisition for the Government. NIH's acquisition strategy used to obtain best value may result in an award to other than the lowest priced, technically rated Offeror. Best value analysis spans a continuum from the lowest priced, technically acceptable proposal to those proposals in which tradeoffs between price, past performance, and each Offeror's technical solution is evaluated. This tradeoff process depends on the Government's assessment of quality factors, including but not limited to past performance, compliance with solicitation requirements, technical excellence, management capability, personnel qualifications and prior experience, and price.

#### **b. NOTICE OF SMALL BUSINESS SET-ASIDE**

1. **General.** Offerors are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.
2. **Definitions.** The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the size standards in this solicitation. In addition to meeting these criteria, a small business concern submitting an offer in his own name shall furnish, in the performing the contract, only end items manufactured or produced by small business concerns in the United States or its outlying areas, provided that this additional requirement does not apply in connection with construction or service contracts.

#### **c. NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is 541712.
2. The small business size standard is 500.

#### **d. TYPE OF CONTRACT AND NUMBER OF AWARDS**

1. It is anticipated that one award will be made from this solicitation and that the award(s) will be made on or about April 4, 2017.
2. It is anticipated that the award from this solicitation will be a Time and Materials type with a 12-month base period and two 12- month option periods.

#### **e. COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

**f. COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this SOLICITATIONS. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

**g. RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

**h. PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

**i. SERVICE OF PROTEST (SEPTEMBER 2006) - FAR 52.233-2**

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

National Institutes of Health

Office of Logistics and Acquisition Operations (OLAO)

Office of Acquisitions, Team 1 Section Chief

6011 Executive Blvd, Suite 529

Rockville, MD 20852

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

**1. Past Performance Information**

a. Offerors shall submit the following information as part of their Technical proposal.

A list of the last three (3) federal government award (contract, purchase orders, task orders), completed during the past 5 years and federal government awards currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

- b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

- a. System for Award Management, FAR Provision 52.204-7 (October 2016).

**Alternate I** (July 2013) is applicable to this solicitation.

- b. Time-and-Materials/Labor-Hour Proposal Requirements-Commercial Item Acquisition, FAR Clause 52.216-31, (February 2007).

## 1. Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

## 2. Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.

8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with FAR 15.406-2.

- a. Data submitted shall be sufficient to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., data to support an analysis of material costs (when sufficient data on labor and overhead rates is already available), or data on prices and quantities at which the offeror has previously sold the same or similar items.

Data submitted must support the price proposed. The offeror shall include sufficient detail or cross references to clearly establish the relationship of the data provided to the price proposed. The offeror shall support any data provided with explanations or supporting rationale, as needed, to permit the Contracting Officer and authorized representative to evaluate the documentation.

- b. The data submitted shall be at the level of detail described below.

- a. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

- b. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

- c. **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over \$750,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

- d. **Raw Materials**

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

- e. **Purchased Parts**

Includes material items not covered above. Provide priced quantities of items required for the proposal.

**f. Fringe Benefits**

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

**g. Indirect Costs**

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

**h. Special Equipment**

If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

**i. Travel**

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

**j. Other Costs**

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

**3. Salary Rate Limitation**

Offerors are advised that no NIH funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II\* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II\*. The Executive Schedule, Level II\* annual salary rate limitation also applies to individuals proposed under subcontracts and to consultants. **LINK TO EXECUTIVE SCHEDULE RATES OF PAY:**

<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/>

*(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

**\*Note to Offerors:** The current Fiscal Year Executive Level II Salary Rate shall be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year Executive Level II Salary rates.

#### 4. **Total Compensation Plan**

##### a. **Instructions**

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

##### b. **Evaluation**

##### 1. **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

##### 2. **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

##### 3. **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

**4. Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees.

**5. Other Administrative Data**

**a. Property**

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below , the proposal must include a comprehensive justification addressing the following items:

- a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
- b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

**2. Government Property**

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

- a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);
- b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
- c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and
- d. A description of the offeror's property management system, plan, and any customary commercial practices, voluntary consensus standards, or industry-leading practices and standards to be used in the offeror in managing Government property.

**NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from an offeror or contractor**

**possessing Government property. This will be done by adjusting the offers by applying, for evaluation purposes only, a rental equivalent evaluation factor, as specified in FAR 52.245-9.**

**b. Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

**6. Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a. Willingness to perform as a subcontractor for specific duties (list duties).
- b. What priority the work will be given and how it will relate to other work.
- c. The amount of time and facilities available to this project.
- d. Information on their cognizant field audit offices.
- e. How rights to publications and patents are to be handled.
- f. A complete cost proposal in the same format as the offeror's cost proposal.

**7. Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

**8. Travel Costs/Travel Policy**

**a. Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

**b. Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.



## **SECTION M - EVALUATION FACTORS FOR AWARD**

### **1. GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

### **2. PRICE EVALUATION**

Offeror(s) price proposal will be evaluated for reasonableness. The proposed price will be evaluated but not scored. The price evaluation will determine whether the proposed prices are fair and reasonable in relation to the solicitation requirements. Proposed prices shall be entirely compatible with the technical quotations.

The degree of importance of the proposed prices will increase with the degree of equality of the proposals in relation to the other factors on which selection is to be based.

### **3. TECHNICAL EVALUATION FACTORS**

The evaluation factors are used by the technical evaluation committee when reviewing the technical proposals. The factors below are listed in the order of relative importance with weights assigned for evaluation purposes. Subfactors are listed in order of relative importance.

#### **1. Technical Approach/Quality of Design - Points 45**

Originality, merit, and feasibility of the proposed method of accomplishing the objectives of the Statement of Work, including discussion of the problems, issues, and scientific efforts associated with the procedures for the following, along with suggested solutions:

Processing the ICSRs and maintaining the database including but not limited to, data entry, image processing and redacting of personal information using a Captiva Input/Accel imaging system, filing of ICSRs.

Insuring the safe and orderly operation of the CAERS work area including equipment use and maintenance of government property; procedures to ensure the security of CAERS data and the facility that houses CAERS equipment and files, both electronic and physical.

#### **2. Personnel Qualifications - Points 35**

The proposal should demonstrate the contractor's experience in providing services to others similar to those outlined in the statement of work. In particular, experience processing ICSRs for the FDA should be detailed. The proposal should demonstrate the contractor's administrative, management, and technical support for activities related to the statement of work as demonstrated by the availability of corporate resources such as technical expertise in processing scientific documents, scientific indexing, data entry, data base maintenance, and development, testing experience in imaging and database management procedures, and initiatives to encourage retention and minimize turnover of qualified personnel.

### 3. Quality Control Procedures - Points 20

Methods to protect the integrity of the projects including: plans to protect the confidentiality of data; plans to assure data integrity; and plans to monitor compliance to protocol.

### 4. PAST PERFORMANCE FACTOR

Offeror's past performance information will be evaluated, but not scored, subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.